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10/729,364	12/05/2003	Raymond W. Sze	UNIV0162	8253

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EXAMINER
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UTAMA, ROBERT J

ART UNIT	PAPER NUMBER
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- 3714

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/08/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/729,364

Applicant(s)

SZE ET AL.

Examiner

Robert J. Utama

Art Unit

3714

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 28-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/05/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTIONS**

### **Status of Claim**

1. In response to the election filed on 12/18/2006, the current status of claims are as follow: claim 1-27 have been elected and claims 28-51 have been withdrawn with traverse

### ***Election/Restrictions***

2. The examiner wish to confirm that claim 28 belongs to group II, that is directed toward method of making an apparatus.

3. Applicant's election with traverse of 1-27 (Group I) in the reply filed on 12/18/2006 is acknowledged. The restriction between group I and III was made under MPEP 806.05(h) instead of MPEP 806.05(e) as mentioned in the applicant's remark. The examiner assumes that the applicant is referring to MPEP 806.05(h). The traversal is on the ground(s) that *"the MPEP requires all the functional and structural elements be used in the analysis of (identifying) materially different process"*. This is not found persuasive because no such requirement can be found in the MPEP. The examiner deemed that applicant fails to proves or provide convincing argument that the alternative used suggested by the examiner cannot be accomplished.

4. Applicant's election with traverse of 1-27 (Group I) in the reply filed on 12/18/2006 is acknowledged. The restriction between group I and II was made under MPEP 806.05(f). The traversal is on the ground(s) that the materially different process suggested by the examiner will not be able to produce visually distinguishable ultrasound image since the molded model will have uniform echogenicity. This is not found persuasive because the molded model can be formed with deep opening or recess to simulate skull sutures. As admitted by the applicants the opening will have

Art Unit: 3714

different echogenicity, which can be observed in the ultrasound model (applicant's argument page 13 line 11-12).

5. Applicant's traversal of the restriction between Group II (claims 28-44) and III in the reply filed on 12/18/2006 is acknowledged. The traversal are on the ground(s) that the examiner fail to set forth different field of search as required by MPEP 806.05(j) and that the examiner has failed to set forth another product that can be successfully used with the method set forth in group III. These arguments are not found persuasive.

The examiner contends that examination of Group II and III will require different field of search. The examiner will be required to do search in the 128/916 (class/subclass) which are directed toward methods of using the ultrasound device in order to produce an ultrasound representation of a human organ/body. However, search on class 128, subclass 916 are not needed in the examination of group II.

The applicants content that a generic skull sutures will be able to show patent skull sutures in an ultrasound examination. The examiner would like to submit evidence that is it possible to adapt a generic medical simulator to produce ultrasound images of patent sutures without the use of the method put forward in Group II (see Bergman 5,609,485). Bergman '485 suggested the use of ultrasound transmitter to feed any desired ultrasound images back to the ultrasound-imaging device (see Bergman abstract).

6. Since the applicant fails to meet the burden to overcome any restriction requirements set forth by the examiner, the requirements are still deemed proper and are therefore made FINAL.

7. Claim 28-51 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/18/2006.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:
- The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
9. Claim 4 is rejected under 35 U.S.C 112, second paragraph, as it lack antecedent basis to support the claim. Claim 4 recites the limitation "a scalp portion" in the ultrasound-training model. There is insufficient antecedent basis for this limitation in the claim. Reference regarding the scalp portion on the model does not exist in its parent claim.
10. The following is a quotation of the first paragraph of 35 U.S.C. 112:
- The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
11. Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 15 discloses two material, first and third material, which are substantially similar in echogenicity. The third material are disclosed in the

Art Unit: 3714

disclosure and claim language as “dimethyl siloxane, hydroxyl-terminated polymers, and silica” or also known as SILLY PUTTY<sup>™</sup>. The disclosure provided fail to provide materials that are substantially similar to the third material.

***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

**13. Claim 1-5 rejected under 35 U.S.C. 102(a) as being anticipated by Infant skull model (NPL #1).**

**Claim 1:** The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, sagittal, coronal and lambdoid sutures. The sutures portion of the model skull is shown as an opening on the model skull. Since the sutures and the model skull are distinguishable from two different materials – open air for the sutures and the plastic model for the skull- the examiner contends this would allow the suture to be readily distinguishable in an ultrasound image.

**Claim 2:** The infant skull model can be seen to be uniformly made from one material and the sutures are simulated by producing an opening of the skull. (see NPL #1).

**Claim 3,4 and 5:** The opening of the sutures are filled with a second material –air- that has a lower echogenicity (or hypoechoic) in comparison to the solid portion of the skull (see NPL #1).

**Claim 20:** NPL #1 contains a photograph of a human infant skull adjacent to an infant. The size of the model in relation to real human skull appears to be relatively the same.

**Claim 21:** The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, sagittal, coronal and lambdoid sutures. The sutures portion of the model skull is shown as an opening on the model skull. Since the sutures and the model skull are distinguishable from two different materials – open air for the sutures and the plastic model for the skull- the examiner contends this would allow the suture to be readily distinguishable in an ultrasound image.

**Claim 22, 23 and 24:** The opening of the sutures are filled with a second material – air- that has a lower echogenicity (or hypoechoic) in comparison to the solid portion of the skull (see NPL #1).

### ***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**15. Claim 7-9, 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Infant skull model (NPL #1).**

**Claim 7-9:** The examiner contends that the reference of NPL #1 fails to show an ultrasound simulator with a patent suture that is filled with a mixture of starch and glue (**claim 7**). Similarly, the reference does not show the glue in the mixture to be a casein-based glue (**claim 8**) or a synthetic resin-based glue (**claim 9**). Instead, the reference NPL #1 shows that the patent sutures are filled with air.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to model the sutures using air or starch and glue mixtures. Furthermore, one of ordinary skilled in the art would have expected to both solutions to work equally well, the echogenicity of both materials are less than then solid portion of the skull.

Therefore, it would have been prima facie obvious to modify NPL #1 to obtain the invention as specified in claim 7-9 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of NPL #1.

**Claim 10 and 11:** The infant skull model (see NPL #1), shows a model substantially about the same size on human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, coronal, sagital and lambdoid sutures. However, the reference fails to show that the each of the sutures opening are beveled.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to model to use beveled opening or any other types of opening (e.g.: flush opening). Furthermore, one of ordinary skilled



Art Unit: 3714

in the art would have expected to both solutions to work equally well, since the type of opening would not matter in its echogenicity properties with respect to an ultrasound device or training.

Therefore, it would have been prima facie obvious to modify NPL #1 to obtain the invention as specified in claim 10 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of NPL #1.

**Claim 26:** The infant skull model (see NPL #1), shows a model substantially about the same size on human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, coronal, sagittal and lambdoid sutures. The reference also shows that the sagittal and metopic sutures are formed in a way that the opposites walls of the opening would meet in an end-to-end fashion.

However, the reference fails to show that the each of the sutures opening are beveled. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to model to use beveled opening or any other types of opening (e.g.: flush opening). Furthermore, one of ordinary skilled in the art would have expected to both solutions to work equally well, since the type of opening would not matter in its echogenicity properties with respect to an ultrasounic device or training.

Therefore, it would have been prima facie obvious to modify NPL #1 to obtain the invention as specified in claim 26 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of NPL #1.

**16. Claim 12-14 and 25 rejected under 35 U.S.C. 103(a) as being unpatentable over Infant skull model (NPL #1) and further in view of Chelue's Fabrication of Medical Model from scan data via rapid prototyping (NPL #2)**

**Claim 12,13 and 27:** The examiner contends that the reference of NPL #1 fails to show an ultrasound simulator with at least one simulated fused skull suture. NPL #2 shows of a 3-Dimensional skull model created from a CT (computer tomography) data of an infant born with a craniosyntosis condition on his/her left side of the skull (see NPL #2 FIG. 5 and the caption). It is inherent from the disclosure that (NPL #2) that the fused sutures would be made of the same material as the rest of the skull (**Claim 13 and 27**).

Therefore, it would have been obvious to modify the infant skull model of (NPL #1) to also include the anatomically correct fused skull suture baby as taught by NPL #2. One of ordinary skill in the art would have been motivated to make this combination since it would allow an effective model in the teaching of young doctors and surgeon (NPL #2 page 3 paragraph 6).

**Claim 14 and 25:** The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The sutures portion of the model skull is shown as an opening on the model skull that is filled with air. The examiner contends that the air and the first material will be able to create ultrasound image that is readily distinguishable. Hence, the examiner contends that the choice of the filling the patent sutures with the third material to indicate fused skull sutures is a matter of design choice.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to fill the sutures with the first material –

Art Unit: 3714

material that the skull is made from- instead of using another material. One of ordinary skill in the art, furthermore, would have expected the first material, and applicant's invention -third material-, to perform equally well in creating an ultrasound image that is not readily distinguishable.

Therefore, it would have been prima facie obvious fill the patent suture with the first material or the third material because such a modification would have been considered a mere design consideration which fails to patentably distinguishable.

**Claim 15-17:** The infant skull model (see NPL #1), does not have a third material that is substantially similar to the in echogenicity with the first material; the first material being the material that the skull model is composed from. Furthermore, where the third material of synthetic elastomer (**claim 16**) and where the elastomer is dimethyl siloxane, hydroxyl-terminated polymers, and silica. The combination of NPL #1 and NPL #2 does not rectify this deficiency.

The examiner contends that the choice of the filling the patent sutures with the third material is a matter of design choice. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to fill the sutures with the first material -material that the skull is made from- instead of using another material. One of ordinary skill in the art, furthermore, would have expected the first material, and applicant's invention -third material-, to perform equally well in creating an ultrasound image that is not readily distinguishable.

Therefore, it would have been prima facie obvious fill the patent suture with the first material or the third material because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art.

**17. Claim 18 rejected under 35 U.S.C. 103(a) as being unpatentable over Infant skull model (NPL #1), in view of Chelue's Fabrication of Medical Model from scan data via rapid prototyping (NPL #2), and further in view of Baldwin US 4,773,865 (hereinafter Baldwin '865).**

**Claim 18:** The infant skull model (see NPL #1) fails to shows an opaque layer which covers a scalp portion of the model. Furthermore, the combination of NPL 1 and NPL 2 fails to rectify this deficiency.

However, Baldwin '865 shows a training mannequin consisting of anatomically correct skeleton covered with a skin like material (Baldwin '865 abstract). The skin covering has the properties that it would allow the student to simulate the tactile sensation of a human body (Baldwin '865 col.2:53-60).

Therefore, it would have been obvious to modify the infant skull model of (NLP #1 as modified by NPL# 2) to also include the feature of having a simulated skin. One of ordinary skilled in the art would have been motivated to make this combination since it would allow the model to simulate the tactile feature of a human infant (Baldwin '865 col.2:53-60).

**18. Claim 19 rejected under 35 U.S.C. 103(a) as being unpatentable over Infant skull model (NPL #1), and further in view of Baldwin US 4,773,865 (hereinafter Baldwin '865).**

**Claim 19:** The infant skull model (see NPL #1) fails to shows an opaque layer which covers a scalp portion of the model.

Art Unit: 3714

However, Baldwin '865 shows a training mannequin consisting of anatomically correct skeleton covered with a skin like material (Baldwin '865 abstract). The skin covering has the properties that it would allow the student to simulate the tactile sensation of a human body (Baldwin '865 col.2:53-60).

Therefore, it would have been obvious to modify the infant skull model of (NLP #1) to also include the feature of having a simulated skin. One of ordinary skilled in the art would have been motivated to make this combination since it would allow the model to simulate the tactile feature of a human infant (Baldwin '865 col.2:53-60).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert J. Utama whose telephone number is (571) 272-1676. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Olszewski can be reached on (571)272-6788. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3714

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